

JUN 25 2008

K081612

510(k) Summary

Date prepared: June 2, 2008

Submitter's name, address, telephone, fax, and contact person:

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Paul Diaz, Vice President of Engineering

Product trade name: Aesculight family of fibers, handpieces, and tips for CO₂ surgical lasers

Product common name: Laser flexible fibers, handpieces, and tips

Classification names: General and Plastic Surgery Devices, 21 CFR, 878.4810, product code GEX; ENT Microsurgical CO₂ Laser, 21 CFR 874.4500, product code EWG; Gynecologic Surgical Laser, 21 CFR 884.4550, product code HHR; Soft Tissue Dental Laser, 21 CFR 878.4810, product code NVK

Legally marketed predicate device: Modified LX-20 Laser System fibers, handpieces, and tips, as described in 510(k) no. K960475

Product description

This is a family of detachable devices that comprise the distal portion of a beam delivery system to be used with a CO₂ surgical laser such as that described in K96075. Specifically, the devices consist of a flexible hollow lightpipe (fiber), handpieces that connect to the fiber, and various tips that connect to the handpieces. The tips are short, rigid hollow alumina lightpipes producing a variety of spot sizes. The user may "mix and match" handpieces and tips to suit the clinical task at hand.

Intended use

The intended use of the product(s) is to communicate the laser beam of a CO₂ surgical laser to the target site for the incision, excision, ablation, or photocoagulation of soft tissue. Representative examples of clinical applications include:

Gynecology--excision and vaporization of cervical, vulvar, and perineal condyloma; ablation of vaginal and vulvar intraepithelial neoplasia; herpes vaporization; vaporization of urethral caruncle; I&D Bartholin's and nubothian cysts

Dermatology--port wine hemangioma removal; rhinophyma reduction; telangiectasia removal; wart removal; basal squamous cell carcinoma removal; blepharoplasty, xanthlasma removal; removal of neurofibromas, hemangiomas, nevi, and trichoepitheliomas; dermabrasion for lentigos, keratoses, actinic keratosis and actinic cheilitis

Dentistry/Oral Surgery--gingivectomy; frenum release; gingivoplasty; removal of soft tissue, cysts, and tumors

General Surgery--hemorrhoid removal; skin tag vaporization; pilonidal cyst removal and repair; debridement of decubitus ulcers and stasis ulcers; mastectomy; breast biopsy, reduction mammoplasty; cytoreduction for metastatic disease; many dermatological procedures

Laparoscopic Surgery--vaporization, incision, excision, ablation, or photo-coagulation of soft tissue such as endometriosis ablation, excision of adhesions, salpingotomy

Otorhinolaryngology--lymphangioma removal; turbinectomy, subglottic stenosis vaporization, tonsillectomy, removal of vocal cord papillomas, nodules, and polyps

Podiatry--plantar wart vaporization; fungal nail treatment; partial and complete matrixectomy; porokeratoma ablation; Morton's neuroma removal; ingrown toenail treatment

Orthopedic--meniscectomy, chondromalacia ablation, partial synovectomy, lateral release, PMMA removal

No new indications for use are sought beyond those associated with the predicate devices.

Technological characterization

When used with a CO₂ laser, the effect on tissue of the laser beam, as produced by the Aesculight family of products, is identical to that of the predicate products. The Aesculight tips produce the same range of spot sizes as the predicate tips. Cosmetically, dimensionally, and ergonomically, the Aesculight products are very similar to the predicates, and use the same optical principles to conduct the laser light from the base unit to the target site. There are, in some cases however, some differences in construction. The predicate fiber is based upon an optically-coated (for enhanced reflectivity) molybdenum ribbon formed into a long skinny tube (with the optical coating on the inside surface), whereas the Aesculight fiber is based upon internally-coated flexible seamless tubing. This tubing, with no seams or gaps in the optical coating, exhibits somewhat better transmission efficiency than the predicate fiber. While some of the Aesculight tips are identical in construction to the predicate tips, some are not. To produce the smaller spot sizes, the predicate tips use a cone of coated molybdenum ribbon to concentrate the beam, whereas the Aesculight tips are monolithic alumina with a conical lumen. The alumina tips are capable of sustaining higher power throughputs than the predicate foil tips. These differences in construction do not introduce any new safety or performance concerns.

The Aesculight handpieces, for the most part, exhibit only minor cosmetic differences to the predicate handpieces. In one case (the backstop handpiece), the Aesculight handpiece is a shorter version of the predicate, and in other cases, Aesculight produces more handpiece models with integral or add-on smoke evacuation capabilities, but these differences merely affect the convenience of use of the handpieces, and have no effect on the laser beam-tissue interaction.

Conclusion

The Aesculight fiber, although differing somewhat in construction, has very similar physical and optical characteristics as the predicate fiber. Both are flexible, optically multi-mode, hollow lightpipes, and both have the same lumen size and length, with the Aesculight version exhibiting superior transmission efficiency. In some cases, the Aesculight handpieces are almost identical to the predicate handpieces; in other cases, the Aesculight handpieces are simple mechanical modifications of the predicate handpieces with the object of providing more convenience for the user. The Aesculight tips are, in some cases, exactly identical to the predicate tips; in other cases, the construction (but not the internal geometry) differs from the predicates, and laboratory bench testing confirms that the spot sizes produced by the Aesculight tips are identical to the predicate tips, that the Aesculight tips have similar transmission efficiencies as the predicate tips and have power-handling capabilities that equal or exceed those of the predicate tips. From a clinical efficacy standpoint, a user could not distinguish a difference between the predicate products and the Aesculight products, nor do the Aesculight products raise any new safety issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2008

Aesculight, LLC
% Mr. Paul Diaz
Vice President of Engineering
16928 Woodinville-Redmond Road Northeast, Suite B104
Woodinville, Washington 98072

Re: K081612
Trade/Device Name: The Aesculight family of flexible fibers, handpieces,
and tips for CO₂ surgical lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 5, 2008
Received: June 9, 2008

Dear Mr. Diaz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

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Device name: The Aesculight family of flexible fibers, handpieces, and tips for CO₂ surgical lasers

Indications for use: Representative examples are listed below.

Gynecology--excision and vaporization of cervical, vulvar, and perineal condyloma; ablation of vaginal and vulvar intraepithelial neoplasia; herpes vaporization; vaporization of urethral caruncle; I&D Bartholin's and nubothian cysts.

Dermatology--port wine hemangioma removal; rhinophyma reduction; telangiectasia removal; wart removal; basal squamous cell carcinoma removal; blepharoplasty, xanthlasma removal; removal of neurofibromas hemangiomas, nevi, and tircoeptheliomas; dermabrasion for lentigos, keratoses, actinic keratosis and actinic chleilitis

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Podiatry--plantar wart vaporization; fungal nail treatment; partial and complete matrixectomy; porokeratoma ablation; Morton's neurome removal; ingrown toenail treatment

Orthopedic--meniscectomy, chondromalacia ablation, partial synovectomy, lateral release, PMMA removal

Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use No
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 16081612

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